MAY 2 1 2014

Section 5: 510(k) Summary K134043

1.0 **Preparation Date:**

December 26, 2013

2.0 **Submitted By:**

KAZ USA, Inc.
250 Turnpike Rd
Southborough, MA 01772

Primary Contact Person/Prepared by:

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250 Turnpike Road,
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3.0 **Device Identification:**

3.1 **Trade Name**

No Touch + Forehead Thermometer

Models:

US: NTF3000US (US Model)

International:
NTF3000CA (Canada), NTF3000WE(Western Europe), NTF3000EE(Eastern Europe), NTF3000AP (Asia Pacific), NTF3000AU(Australia), NTF3000(Korea), NTF3000CN(China)

3.2 **Common Name**

Contact Skin Surface Thermometer

3.3 **Classification Name**

Thermometer, Clinical, Electronic
(21CFR 880.2910: Product code - FLL)

4.0 **Predicate Device:**

Predicate	Manufacturer	Docket Number
Safety 1st ProGrade Health No Touch Thermometer	Safety 1st (Avita)	K081160

5.0 **Device Description:**

The No Touch+Forehead Thermometer (Model NTF3000US) is a hand-held, battery powered device designed to measure human body temperature. The NTF3000 is an Infrared thermometer that converts a user's forehead temperature using the infrared energy emitted in the area around the user's forehead to an oral equivalent temperature when placed in contact with the subject's forehead or up to two (2) inches away.

The NTF 3000 thermometer uses a thermopile sensor with integrated thermistor for the target reading, a thermistor mounted in the head of the thermometer for ambient temperature readings, a parabolic mirror to help focus the infrared energy emitted from the forehead, and an infrared distance sensor for detection of contact or non-contact use and compensation of the temperature reading.

6.0 **Intended Use:**

The No Touch + Forehead Thermometer (Model NTF3000US) is a non-sterile, reusable clinical thermometer intended for the intermittent determination of human body temperature in a touch and no touch on the centre of the forehead as the measurement site on people of all ages.

7.0 **Statement to Conform to the Consensus Standards (Verification)**

The No Touch + Forehead Thermometer conforms to the following FDA recognized consensus standards and other standards that include:

1) ASTM E1965-2009 Infrared Thermometers for Intermittent Determination of Patient temperature and;

2) Clinical accuracy test requirements established in the standard of ASTM E1965-03 (Clinical part only)- Standard Specification for Infrared Thermometer for Intermittent Determination of Patient Temperature;

3) IEC 60601-1 3rd edition: Medical Electrical Equipment: General requirements for Safety, Requirements and Tests.

4) IEC 60601-1-2: Medical Electrical Equipment- Part 1: General Requirements for Safety, Electromagnetic Compatibility- Requirements and Tests.

5) AAMI / ANSI / ISO 10993-1:2003(E), Biological evaluation of medical devices -- Part 1: Evaluation and testing- and appropriate Parts

6) ISO 10993-5: Biological Evaluation of Medical Devices: Part 5: Tests for In-vitro cytotoxicity.
7) ISO 10993-10: Biological Evaluation of Medical Devices: Part 10: Tests for Irritation and Sensitization.
8) ISO 14971:2007 2nd edition: Application of Risk Management to Medical Devices
9) EN62304:2006 Medical device software – Software life-cycle processes (IEC 62304:2006); [*German version EN 62304:2006, Corrigendum to DIN EN 62304 (VDE 0750-101):2007- 03; German version CENELEC-Cor.: 2008 to EN 62304:2006]*
10) EN60601-1-6:2009 General requirements for basic safety and essential performance – Collateral Standard: Usability
11) FDA compliance 510(k) – per 21CFR 807, subpart E, 21 CFR 820, clinical report per 21 CFR 812
12) ISO 14155:2011 Clinical investigation of medical devices for human subjects — Good Clinical Practice

Data supporting conformance with these standards is available from KAZ Inc and is attached as part of this submission.

8.0 **Validation Results:**

Clinical Study to show substantial equivalence:
A comparison study and clinical repeatability testing was performed on the following four age groups: 0-12 months, 12 months- <5 years, 5 years- <18 years, and 18 years and older in accordance with ASTM E1965-03 to compare the No Touch+Forehead Thermometer with the predicate Safety 1st ProGrade Health No Touch Thermometer (K081160). The reference or the gold standard used was the Braun Infra Red Ear Pro 4000 Series Thermometer (K031968/K101747/K103800). This clinical comparison study demonstrated that the No Touch+Forehead Thermometer is as good as (non-inferior or substantially equivalent to) the previously approved Safety 1st ProGrade Health No Touch Thermometer in all age groups with respect to the bias and standard deviation in comparison to the Braun Infra Red Ear Pro 4000 Series Thermometer. The temperatures obtained with the No Touch + Forehead Thermometer were highly related when compared to the predicate device, where temperatures were measured at forehead sites. The clinical bias with stated uncertainty and clinical repeatability as defined in the ASTM E1965-03 standard were within clinical acceptability (bias less than predicate device when compared to reference). The clinical repeatability of the No Touch + Forehead Thermometer was statistically and clinically acceptable (less than 0.3 deg C or 0.58 deg F). Please see sections M and L for the detailed protocol and report for the substantial equivalence study.

9.0 **Conclusion:**

Based on the safety and performance testing and the compliance with the acceptable voluntary consensus standards, we conclude that the No Touch+Forehead Thermometer Thermometer is substantially equivalent to its predicate device cited above and does not raise any new questions of safety and/or effectiveness.

10.0 **Similiarities/Differences of the proposed candidate device when compared to the predicate:**

10.1 Intended Use

The predicate device, the Safety 1st ProGrade Health No Touch Thermometer is intended for the intermittent determination of the human's body temperature for people of all ages. The intended use and indications for use of the predicate and the Kaz No Touch + Forehead Thermometer are similar. The predicate device uses the temple area of the forehead while the Kaz "No Touch + Forehead Thermometer" uses the centre of the forehead as the measurement site.

10.2 Materials

Materials used in the manufacture of the KAZ Thermometer are similar to the predicate device. All skin contacting materials used in the new thermometer have been tested in accordance with ISO 10993-1 and FDA Blue book memo G 95-1 for both Thermometers and the corresponding test reports are included in this submission.

10.3 Design

The design of the KAZ Thermometer is technologically similar to the predicate device but uses a parabolic mirror to focus the infrared energy on the sensor.

10.4 Operational Principles

The KAZ Thermometer is a handheld device, containing an On/Off switch, sensor area, microcontroller and LCD screen to control the device and take measurements. The operating principle is based on detection of infrared energy and use of predictive algorithms to estimate the body temperature.

10.5 Technology

A technology similar to that of the predicate was used in the design of the No Touch + Forehead Thermometer is employed in the design of the predicate device. The key difference is that the Kaz thermometer uses a parabolic mirror to focus the infrared energy collected from the forehead on the infrared sensor.

10.6 **Safety and Performance**

KAZ has provided statements that its No Touch + Forehead Thermometer conforms to the following FDA recognized consensus standards and other standards that include:

Standard or Guidance Document	Data Generated	Relevant Section of Submission
Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s FDA compliance 510(k) – per 21CFR 807, subpart E, 21 CFR 820, clinical report per 21 CFR 812	Submission Format	All
ASTM E1965-09- Standard Specification for Infrared Thermometer for Intermittent Determination of Patient Temperature.	Clinical Data/Declaration of Conformity	Appendix I
IEC/ISO/EN 60601-1-1-2:2007 Medical Electrical Equipment- Part 1 General Requirements for Safety, Electromagnetic Compatibility-Requirements and Tests	EMC Data/Declaration of Conformity	Appendix H
IEC/ISO/EN 60601-1:2005 & -11: 2010 Medical Electrical Equipment- Part 1 General Requirements for Electrical Safety, Requirements and Tests	Electrical Safety Data/Declaration of Conformity	Appendix G
IEC EN60601-1-6:2010 General requirements for basic safety and essential performance – Collateral Standard: Usability FDA Human Factors Draft Guidance Document: Agency Expectations for Human Factors Data in Premarket Submissions – March 21, 2012	Usability Protocol & Report	Appendix N
AAMI / ANSI / ISO 10993-1:2009, Biological evaluation of medical devices -- Part 1: Evaluation and testing And FDA Blue book memo G95-1 on Biocompatibility	Biocompatibility Data/Declaration of Conformity	Appendix F
AAMI / ANSI / ISO 10993-5:2009, Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity	Cytotoxicity Data	Appendix F

AAMI / ANSI / ISO 10993-10:2010, Biological evaluation of medical devices — Part 10: Tests for irritation and delayed-type hypersensitivity	Irritation Data & Sensitization Data	Appendix F
ISO 14971:2012 Application of Risk Management to Medical Devices	Declaration of Conformity	Appendix Q
EN62304:2006 Medical device software Software life-cycle processes (IEC 62304:2006)	EN62304 Index in Appendix J	Appendix J
21CFR 812, 50 and 56 and ISO 14155:2011 Clinical investigation of medical devices for human subjects — Good Clinical Practice	Clinical Agreements, IRB and Informed Consent	Appendix K, L, M

11.0 **Similarities/Differences of the proposed candidate device when compared to th predicate:**

Aspects	Predicate	Candidate
Classification	21CFR 880.2910	Same
Product Code	FLL	Same
FDA Class	II	Same
Intended Use	A non-sterile, reuseable clinical thermometer intended for the determination of the human's body temperature for people of all ages.	A non-sterile, re-useable clinical thermometer intended for the intermittent determination of the human's body temperature for people of all ages.
Operation	Hand held-Manually operated	Same
Sensor	Infrared	Same
Materials	Common Materials- including an impact resistant casing. Biocompatible metals and resins.	Same
Standards Met for Bench and Clinical Performance	ASTM E1965-98:2009 ..... Infrared Thermometers for Intermittent Determination of Patient Temperature. The clinical accuracy test section of ASTM E1965-09- Standard Specification for Infrared Thermometer for Intermittent Determination of Patient Temperature.	Same
Standards met for Safety	1) IEC 60601-1 3rd edition:2005 and -11: 2010 Medical Electrical Equipment: General requirements for Safety, Requirements and Tests. 2) IEC 60601-1-2:2007 Medical Electrical Equipment- Part 1: General Requirements for Safety, Electromagnetic Compatibility- Requirements and Tests. 3) AAMI / ANSI / ISO 10993-1:2009, Biological evaluation of medical devices -- Part 1: Evaluation and testing- and appropriate Parts 4) ISO 10993-5:2009 Biological Evaluation of Medical Devices: Part 5: Tests for In-vitro cytotoxicity. 5) ISO 10993-10:2010 Biological Evaluation of Medical Devices: Part 10: Tests for Irritation and Sensitization. 6) ISO 14971:2012: Application of Risk Management to Medical Devices 7) IEC EN 60601-1-6:2010 General requirements for basic safety and essential performance – Collateral Standard: Usability 8) FDA Human Factors Draft Guidance Document: Agency Expectations for Human Factors Data in Premarket Submissions –March 21, 2012	Same

12. Conclusion:

Based on the safety and performance testing and compliance with acceptable voluntary standards, we believe that the "No Touch + Forehead" Thermometer is substantially equivalent to its predicate device cited above and does not raise any new safety and/or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

May 21, 2014

Kaz USA, Incorporated
Mr. Raj S. Kasbeker
Vice President, Regulatory Affairs
250 Turnpike Road
Southborough, MA 01772

Re: K134043
Trade/Device Name: NTF 3000 No Touch+ Forehead Infrared Thermometer
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical electronic thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: April 21, 2014
Received: April 24, 2014

Dear Mr. Kasbeker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K134043

Device Name
NTF 3000 No Touch+ Forehead Thermometer

Indications for Use *(Describe)*

The No Touch + Forehead Thermometer (Model NTF3000US) is a non-sterile, reusable clinical thermometer intended for the intermittent determination of human body temperature in a touch and no touch mode on the centre of the forehead as the measurement site on people of all ages.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Digitally signed by Richard C. Chapman
Date: 2014.05.21 13:29:25 -04'00'

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